General

Guideline Title

Practice guidelines for preoperative fasting and the use of pharmacologic agents to reduce the risk of pulmonary aspiration: application to healthy patients undergoing elective procedures. An updated report by the American Society of Anesthesiologists Committee on Standards and Practice Parameters.

Bibliographic Source(s)

American Society of Anesthesiologists Committee on Standards and Practice Parameters. Practice guidelines for preoperative fasting and the use of pharmacologic agents to reduce the risk of pulmonary aspiration: application to healthy patients undergoing elective procedures: an updated report [trunc]. Anesthesiology. 2011 Mar;114(3):495-511. [71 references] PubMed

Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: American Society of Anesthesiologists. Practice guidelines for preoperative fasting and the use of pharmacologic agents to reduce the risk of pulmonary aspiration: application to healthy patients undergoing elective procedures. Anesthesiology 1999 Mar;90(3):896-905.

Recommendations

Major Recommendations

Fasting Recommendations

Ingested Material	Minimum Fasting Period
Clear liquids	2 hours
Breast milk	4 hours
Infant formula	6 hours
Nonhuman milk	6 hours
Light meal	6 hours

These recommendations apply to healthy patients who are undergoing elective procedures. They are not intended for women in labor. Following

the Guidelines does not guarantee complete gastric emptying. The fasting periods noted above apply to patients of all ages.

Examples of clear liquids include water, fruit juices without pulp, carbonated beverages, clear tea, and black coffee. Because nonhuman milk is similar to solids in gastric emptying time, the amount ingested must be considered when determining an appropriate fasting period.

A light meal typically consists of toast and clear liquids. Meals that include fried or fatty foods or meat may prolong gastric emptying time. Additional fasting time (e.g., 8 hours or more) may be needed in these cases. Both the amount and type of food ingested must be considered when determining an appropriate fasting period.

Pharmacologic Recommendations

These recommendations are listed by medication type with common examples. In addition, combinations of the medications listed are not recommended for routine use.

Gastrointestinal Stimulants

Metoclopramide: No routine use

Gastric Acid Secretion Blockers

- Cimetidine: No routine use
- Famotidine: No routine use
- Ranitidine: No routine use
- Omeprazole: No routine use
- Lansoprazole: No routine use

Antacids

- Sodium citrate: No routine use
- Sodium bicarbonate: No routine use
- Magnesium trisilicate: No routine use

Antiemetics

- Droperidol: No routine use
- Ondansetron: No routine use

Anticholinergics

- Atropine: No use
- Scopolamine: No use
- Glycopyrrolate: No use

Multiple Agents

No routine use

Clinical Algorithm(s)

None provided

Scope

Disease/Condition(s)

Pulmonary aspiration

Guideline Category

Evaluation

Prevention

Clinical Specialty

Anesthesiology

Family Practice

Internal Medicine

Nursing

Pulmonary Medicine

Surgery

Intended Users

Advanced Practice Nurses

Allied Health Personnel

Health Care Providers

Nurses

Physicians

Guideline Objective(s)

- To enhance the quality and efficiency of anesthesia care
- To stimulate evaluation of clinical practices
- To reduce the severity of complications related to perioperative pulmonary aspiration of gastric contents

Target Population

Healthy patients of all ages undergoing elective procedures

Note: These Guidelines do not apply to patients who undergo procedures with no anesthesia or only local anesthesia when upper airway protective reflexes are not impaired, and when no risk factors for pulmonary aspiration are apparent. These Guidelines are also not intended for women in labor. These guidelines may not apply to, or may need to be modified for patients with coexisting diseases or conditions that can affect gastric emptying or fluid volume (e.g., pregnancy, obesity, diabetes, hiatal hernia, gastroesophageal reflux disease, ileus or bowel obstruction, emergency care, enteral tube feeding) and patients in whom airway management might be difficult.

Interventions and Practices Considered

1. Preoperative assessment (e.g., history, physical examination, survey/interview)
2. Preoperative fasting periods for solids and liquids (clear liquids, breast milk, infant formula, solids and non-human milk)
3. Preoperative gastrointestinal stimulants (e.g., metoclopramide) for reducing gastric volume (not recommended for routine use)
4. Preoperative pharmacologic blockade of gastric acid secretion (e.g., histamine-2 receptor antagonists, proton pump inhibitors (not recommended for routine use)

5. Preoperative antacids (sodium citrate, sodium bicarbonate, or magnesium trisilicate) (not recommended for routine use)
6. Preoperative antiemetics (droperidol, ondansetron), anticholinergics (atropine, scopolamine, or glycopyrrolate), and multiple agents (not recommended for routine use)

Major Outcomes Considered

- Adverse consequences of pulmonary aspiration (pneumonia, respiratory disabilities, related morbidity)
- Volume and acidity of gastric contents
- Adverse effects (e.g., thirst, hunger, nausea, vomiting)
- Adverse outcomes (e.g., pneumonitis, mortality)
- Length of hospital stay
- Costs

Methodology

Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Hand-searches of Published Literature (Secondary Sources)

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

State of the Literature

For these Guidelines, a literature review is used in combination with opinions obtained from expert consultants and other sources (e.g., American Society of Anesthesiologists members, open forums, Internet postings). Both the literature review and opinion data are based on evidence linkages, or statements regarding potential relationships between clinical interventions and outcomes. The interventions listed be-low were examined to assess their impact on pulmonary aspiration and other outcomes. Outcomes for the listed interventions include, but are not limited to, pulmonary aspiration, volume and acidity of gastric contents, adverse effects (e.g., thirst, hunger, nausea, vomiting), adverse out-comes (e.g., pneumonitis, mortality), and other outcomes (e.g., length of stay in hospital, costs).

Preoperative Assessment

1. Medical record review or patient condition
2. Physical examination
3. Patient survey/questionnaire

Preoperative Fasting Status

1. Adults: Clear liquids between 2 and 4 h versus more than 4 h
2. Children: Clear liquids between 2 and 4 h versus more than 4 h
3. Breast milk between 2 and 4 h versus more than 4 h
4. Infant formula between 2 and 4 h versus more than 4 h
5. Solids or nonhuman milk less than 4 h versus more than 4 h
6. Solids or nonhuman milk between 4 and 8 h versus more than 8 h

Preoperative Pharmacologic Interventions

1. Gastrointestinal stimulants (e.g., metoclopramide, cisapride)
2. Blockage of gastric acid secretion
    a. Histamine-2 receptor antagonists (e.g., cimetidine, ranitidine, famotidine)

b. Proton pump inhibitors (e.g., omeprazole, lansoprazole)
3. Antacids (e.g., sodium citrate, magnesium trisilicate)
4. Antiemetics (e.g., ondansetron, droperidol)
5. Anticholinergics (e.g., atropine, glycopyrrolate)
6. Multiple agents/drugs versus single agents/drugs

For the literature review, potentially relevant clinical studies were identified via electronic and manual searches of the literature. For the original Guidelines, electronic and manual searches covered a 57-yr period from 1940 through 1996. The literature search for this update covered the 15-yr period from 1996 through 2010 and included review of 1,223 non-overlapping articles that addressed topics related to the evidence linkages. After review of the articles, 1,065 studies did not provide direct evidence and were subsequently eliminated. A total of 158 articles contained findings directly related to at least one of the evidence linkages listed above. No evidence linkage contained sufficient literature with well-defined experimental designs and statistical information to conduct an analysis of aggregated studies (i.e., meta-analysis). A complete bibliography used to develop these updated Guidelines, organized by section, is available as Supplemental Digital Content 2, http://links.lww.com/ALN/A661 .

Number of Source Documents

A total of 158 articles contained findings directly related to at least one of the evidence linkages listed.

Methods Used to Assess the Quality and Strength of the Evidence

Expert Consensus

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Preparation of this update used the same methodologic process as was used in the original Guidelines to obtain new evidence from two principal sources: scientific evidence and opinion-based evidence (see appendix 2 in the original guideline document). The protocol for reporting each source of evidence is described below.

Scientific Evidence

Study findings from published scientific literature were aggregated and are reported in summary form by evidence category, as described below. All literature (e.g., randomized controlled trials, observational studies, case reports) relevant to each topic was considered when evaluating the findings. However, for reporting purposes in this document, only the highest level of evidence (i.e., level 1, 2, or 3 within category A, B, or C) is included in the summary.

Category A: Supportive Literature

Randomized controlled trials report statistically significant ($P < 0.01$) differences between clinical interventions for a specified clinical outcome.

Level 1. The literature contains multiple randomized controlled trials. Aggregated findings are supported by meta-analysis.*

Level 2. The literature contains multiple randomized controlled trials, but there is an insufficient number of studies to conduct a viable meta-analysis for the purpose of these Guidelines.

Level 3. The literature contains a single randomized controlled trial.

*All meta-analyses are conducted by the ASA methodology group. Meta-analyses from other sources are reviewed but not included as evidence in this document.

Category B: Suggestive Literature

Information from observational studies permits inference of beneficial or harmful relationships among clinical interventions and clinical outcomes.

Level 1. The literature contains observational comparisons (e.g., cohort, case control research designs) of clinical interventions or conditions and

indicates statistically significant differences between clinical interventions for a specified clinical outcome.

Level 2. The literature contains non-comparative observational studies with associative (e.g., relative risk, correlation) or descriptive statistics.

Level 3. The literature contains case reports.

Category C: Equivocal Literature

The literature cannot determine whether there are beneficial or harmful relationships among clinical interventions and clinical outcomes.

Level 1. Meta-analysis did not find significant differences among groups or conditions.

Level 2. The number of studies is insufficient to conduct meta-analysis, and (1) randomized controlled trials have not found significant differences among groups or conditions, or (2) randomized controlled trials report inconsistent findings.

Level 3. Observational studies report inconsistent findings or do not permit inference of beneficial or harmful relationships.

Category D: Insufficient Evidence from Literature

The lack of scientific evidence in the literature is described using the terms defined below.

Silent. No identified studies address the specified relationships among interventions and outcomes.

Inadequate. The available literature cannot be used to assess relationships among clinical interventions and clinical outcomes. The literature either does not meet the criteria for content as defined in the "Focus" of the Guidelines or does not permit a clear interpretation of findings due to methodological concerns (e.g., confounding in study design or implementation).

Opinion-based Evidence

All opinion-based evidence relevant to each topic (e.g., survey data, open forum testimony, Internet-based comments, letters, editorials) was considered in the development of the original Guidelines. New opinion surveys were developed to address each clinical intervention identified in the document, and identical surveys were distributed to both expert consultants and a random sample of active American Society of Anesthesiologists (ASA) members.

Category A: Expert Opinion

Survey responses from Task Force appointed expert consultants are reported in summary form in the text. A complete listing of consultant survey responses reported in a table in appendix 2 of the original guideline document.

Category B: Membership Opinion

Survey responses from active ASA members are reported in summary form in the text. A complete listing of ASA member survey responses reported in appendix 2 in the original guideline document.

Survey responses are recorded using a 5-point scale and summarized based on median values.**

- *Strongly Agree*. Median score of 5 (at least 50% of responses are 5).
- *Agree*. Median score of 4 (at least 50% of responses are 4 [or 4 and 5]).
- *Equivocal*. Median score of 3 (at least 50% of responses are 3— or no other response category or combination of similar categories contain at least 50% of responses).
- *Disagree*. Median score of 2 (at least 50% of responses are 2 [or 1 and 2]).
- *Strongly Disagree*. Median score of 1 (at least 50% of responses are 1).

Category C: Informal Opinion

Open-forum testimony, Internet-based comments, letters, and editorials were all informally evaluated and discussed during the development of the original Guideline recommendations.

**When an equal number of categorically distinct responses are obtained, the median value is determined by calculating the arithmetic mean of the two middle values. Ties are calculated by a predetermined formula.

Methods Used to Analyze the Evidence

Meta-Analysis

Other

Systematic Review

Description of the Methods Used to Analyze the Evidence

The literature is categorized according to the proximity or directness of the outcome to the intervention. To appropriately evaluate an outcome, a study should either evaluate a direct comparison or institute methodological controls (e.g., control for intervening variables). For these Guidelines, the primary outcomes of interest are pulmonary aspiration and its adverse consequences. Therefore, these Guidelines focus on assessing the causal relationship between a preoperative intervention and the frequency of pulmonary aspiration, and assessing the causal relationship between a preoperative intervention and the frequency or severity of an adverse consequence associated with aspiration (e.g., pneumonitis). However, the literature is insufficient to evaluate such relationships. The literature reveals four types of analytic relationships between preoperative interventions and outcomes of interest. These types of relationships are referred to as first-, second-, third-, or fourth-order comparisons.

A first-order comparison represents a direct comparison either between an intervention (e.g., antacid administration) and a clinical outcome, or between two outcomes (e.g., gastric volume and emesis). In the studies reviewed with first-order comparisons, the relationship between one of the identified interventions in the Guidelines and the incidence of pulmonary aspiration was not assessed. Therefore, a cause-and-effect relationship between an intervention of interest and pulmonary aspiration cannot be shown. Although some outcomes (e.g., gastric volume, pH) were considered by the authors to be representative of a predicted risk of pulmonary aspiration, results of such comparisons are not sufficient to provide methodologically acceptable evidence.

Levels 2 through 4 represent comparisons that must first control for an intermediate outcome. For example, to examine the effectiveness of a histamine-2 receptor antagonist on pulmonary aspiration, the effect of the histamine-2 receptor antagonist on gastric content as well as the occurrence of emesis must be methodologically controlled. Gastric content and emesis "outcomes" are intervening steps between the intervention and pulmonary aspiration. This example would be considered a third-order comparison.

Level 2 represents a comparison in which one step, or inter-mediate outcome, exists between the intervention and the out-come of interest. However, level 2 relationships do not examine the association between an intervention of interest and the occurrence of pulmonary aspiration.

Level 3 contains one relationship of interest to the Guide-lines (i.e., intervention/pulmonary aspiration).

Level 4 contains the other relationship of interest to the Guidelines (i.e., association between an intervention and clinical consequences from pulmonary aspiration). Table 1 in the original guideline document indicates that outcomes related to preoperative fasting and the administration of pharmacologic agents were insufficient to evaluate cause-and-effect relationships that link the interventions of interest in these Guidelines with the occurrence of pulmonary aspiration or the clinical consequences from pulmonary aspiration.

Although the literature was not sufficient for causal assessment related to pulmonary aspiration, findings for each intervention of interest regarding intermediate outcomes is reported. Initially, each pertinent outcome reported in a study is classified as supporting an evidence linkage, refuting a linkage, or equivocal. These results are then summarized to obtain a directional assessment for each evidence linkage before conducting a formal meta-analysis. The literature relating to five evidence linkages contained enough studies with well-defined experimental designs and statistical information to conduct formal meta-analyses. These five evidence linkages are: (1) preoperative fasting status of liquids between 2 and 4 h for adults, (2) preoperative fasting status of liquids between 2 and 4 h for children, (3) preoperative metoclopramide, (4) preoperative cimetidine, and (5) preoperative ranitidine. Meta-analysis was limited to gastric volume and acidity outcomes (see table 2 in the guideline document).

General variance-based effect-size estimates or combined probability tests are obtained for continuous outcome measures. Mantel-Haenszel odds ratios are obtained for dichotomous outcome measures. Two combined probability tests are used as follows: (1) the Fisher combined test, producing chi-square values based on logarithmic transformations of the reported P values from the independent studies, and (2) the Stouffer combined test, providing weighted representations of the studies by weighting each of the standard normal deviates by the size of the sample. An odds-ratio procedure based on the Mantel-Haenszel method for combining study results using 2 x 2 tables is used with outcome frequency information. An acceptable significance level is set at a P value of less than 0.01 (one-tailed). Tests for heterogeneity of the in-dependent studies are conducted to ensure consistency among study results. DerSimonian-Laird random-effects odds ratios are obtained when significant heterogeneity is found ($P < 0.01$). To control for potential publishing bias, a "fail-safe n value" is calculated. No search for unpublished studies was conducted; no reliability tests for locating research results were done. To be accepted as significant findings, Mantel-Haenszel odds ratios must

agree with combined test results whenever both types of data are assessed. In the absence of Mantel-Haenszel odds ratios, findings from the Fisher and weighted Stouffer combined tests must agree with each other to be considered statistically significant.

For the original Guidelines, interobserver agreement among Task Force members and two methodologists was established by interrater reliability testing. Agreement levels using a kappa (k) statistic for two-rater agreement pairs are as follows: (1) type of study design, k = 0.75 – 0.95; (2) type of analysis, k = 0.54 – 0.85; (3) evidence linkage assignment, k = 0.68 – 0.82; and (4) literature inclusion for database, k = 0.64 – 0.78. Three-rater chance-corrected agreement values are: (1) design, Sav k = 0.81, Var (Sav) k = 0.006; (2) analysis, Sav k = 0.66, Var (Sav) k = 0.014; (3) linkage identification, Sav k = 0.75, Var (Sav) k = 0.005; (4) literature database inclusion, Sav k = 0.67, Var (Sav) k = 0.050. These values represent moderate to high levels of agreement.

Consensus-based Evidence

Consensus was obtained from multiple sources, including: (1) survey opinion from consultants who were selected based on their knowledge or expertise in preoperative fasting and prevention of pulmonary aspiration, (2) survey opinions solicited from active members of the American Society of Anesthesiologists, (3) testimony from attendees of a publicly held open forum for the original Guidelines held at a national anesthesia meeting, (4) Internet commentary, and (5) Task Force opinion and interpretation. The survey rate of return was 59.7% (37 of 62) for the consultants (see table 3 in the original guideline document); 471 responses were received from active American Society of Anesthesiologists members (see table 4 in the original guideline document).

For the original Guidelines, an additional survey was sent to the consultants asking them to indicate which, if any, of the evidence linkages would change their clinical practices if the Guidelines were instituted. The percent of consultants expecting no change associated with each linkage were as follows: preoperative assessment, 95%; preoperative fasting of solids, 75%; preoperative fasting of liquids, 67%; preoperative fasting of breast milk, 78%; gastrointestinal stimulants, 95%; pharmacologic blockage of gastric secretion, 91%; antacids, 100%; antiemetics, 98%, anticholinergics, 100%, and multiple agents, 98%. Ninety-six percent of respondents indicated that the Guidelines would have no effect on the amount of time spent on a typical case. For all respondents, the mean increase in the amount of time spent on a typical case was 2.4 min. Two respondents reported that the Guidelines would increase the amount of time spent per case. The anticipated time increase for these two respondents was 5 and 120 min, respectively.

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

The original Guidelines were developed by a Task Force of 10 members, including anesthesiologists in both private and academic practice from various geographic areas of North America, and a consulting methodologist from the American Society of Anesthesiologists (ASA) Committee on Standards and Practice Parameters.

The Task Force developed the original Guidelines by means of a six-step process. First, they reached consensus on the criteria for evidence. Second, original published research studies from peer-reviewed journals relevant to preoperative fasting were reviewed and evaluated. Third, expert consultants were asked (1) to participate in opinion surveys on the effectiveness of various preoperative fasting management recommendations and (2) to review and comment on a draft of the Guidelines. Fourth, the Task Force held open forums at a national meeting† to solicit input on the draft recommendations. Fifth, expert consultants were surveyed to assess their opinions on the feasibility of implementing the Guidelines. Sixth, all available information was used to build consensus within the Task Force to finalize the Guideline recommendations (see appendix 1 in the original guideline document).

In 2009, the ASA Committee on Standards and Practice Parameters requested that scientific evidence for these Guidelines be updated. This update consists of an evaluation of literature that includes new studies obtained after publication of the original Guidelines, new surveys of expert consultants, and a survey of a randomly selected sample of active ASA members.

†12th Annual Meeting of the Society for Ambulatory Anesthesia, Orlando, Florida, May 2, 1997.

Rating Scheme for the Strength of the Recommendations

Not applicable

Cost Analysis

A formal cost analysis was not performed and published cost analyses were not reviewed.

Method of Guideline Validation

External Peer Review

Internal Peer Review

Description of Method of Guideline Validation

Expert consultants were asked (1) to participate in opinion surveys on the effectiveness of various preoperative fasting management recommendations and (2) to review and comment on a draft of the Guidelines.

The Task Force held open forums at a national meeting to solicit input on the draft recommendations and expert consultants were surveyed to assess their opinions on the feasibility of implementing the Guidelines. All available information was used to build consensus within the Task Force to finalize the Guideline.

This Practice Guideline was approved by the American Society of Anesthesiologists House of Delegates on October 20, 2010.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

Evidence was obtained from two principal sources: scientific evidence and opinion-based evidence.

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Enhanced quality and efficiency of anesthesia care including the following benefits:

- Decreased frequency and severity of complications related to pulmonary aspiration of gastric contents
- Cost-effective utilization of perioperative preventive medication
- Increased patient satisfaction
- Avoidance of delays and cancellations
- Decreased risk of dehydration or hypoglycemia from prolonged fasting
- Minimization of perioperative morbidity

Potential Harms

Fasting is associated with risk of dehydration and hypoglycemia.

Qualifying Statements

Qualifying Statements

Practice Guidelines are systematically developed recommendations that assist the practitioner and patient in making decisions about health care.

These recommendations may be adopted, modified, or rejected according to clinical needs and constraints and are not intended to replace local institutional policies. In addition, Practice Guidelines developed by the American Society of Anesthesiologists (ASA) are not intended as standards or absolute requirements, and their use cannot guarantee any specific outcome. Practice Guidelines are subject to revision as warranted by the evolution of medical knowledge, technology, and practice. They provide basic recommendations that are supported by synthesis and analysis of the current literature, expert and practitioner opinion, open forum commentary, and clinical feasibility data.

Implementation of the Guideline

Description of Implementation Strategy

An implementation strategy was not provided.

Implementation Tools

Resources

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Staying Healthy

IOM Domain

Effectiveness

Safety

Identifying Information and Availability

Bibliographic Source(s)

American Society of Anesthesiologists Committee on Standards and Practice Parameters. Practice guidelines for preoperative fasting and the use of pharmacologic agents to reduce the risk of pulmonary aspiration: application to healthy patients undergoing elective procedures: an updated report [trunc]. Anesthesiology. 2011 Mar;114(3):495-511. [71 references] PubMed

Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

1999 (revised 2011 Mar)

Guideline Developer(s)

American Society of Anesthesiologists - Medical Specialty Society

Source(s) of Funding

American Society of Anesthesiologists

Guideline Committee

American Society of Anesthesiologists Committee on Standards and Practice Parameters

Composition of Group That Authored the Guideline

Committee Members: Jeffrey L. Apfelbaum, M.D. (*Chair*), Chicago, Illinois; Robert A. Caplan, M.D., Seattle, Washington; Richard T. Connis, Ph.D., Woodinville, Washington; Burton S. Epstein, M.D., Washington, D.C.; David G. Nickinovich, Ph.D., Bellevue, Washington; and Mark A. Warner, M.D., Rochester, Minnesota

Financial Disclosures/Conflicts of Interest

Not stated

Guideline Endorser(s)

Not applicable - Not stated

Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: American Society of Anesthesiologists. Practice guidelines for preoperative fasting and the use of pharmacologic agents to reduce the risk of pulmonary aspiration: application to healthy patients undergoing elective procedures. Anesthesiology 1999 Mar;90(3):896-905.

Guideline Availability

Electronic copies: Available in Portable Document Format (PDF) and EPUB for eBook devices from the Anesthesiology Journal Web site .

Print copies: Available from the American Society of Anesthesiologists, 520 N. Northwest Highway, Park Ridge, IL 60068-2573.

Availability of Companion Documents

None available

Patient Resources

None available

NGC Status

This summary was completed by ECRI on May 31, 1999. The information was verified by the guideline developer on July 14, 1999. This NGC summary was updated by ECRI Institute on December 13, 2011.

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